GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2679
ANSWERED ON:10.08.2005
QUALITY OF MEDICAL DIAGNOSTIC KITS
Dhanaraju Dr. K.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) Whether the Medical Diagnostic Kits are procured through tenders by the NTPC for NACO;

(b) if so, the guidelines laid down for the quality of Medical Diagnostic Kits alongwith its cost;

(c) whether NTPC which is a non-medical organization conducts quality control checks on Medical Diagnostic Kits viz., HIV, HCV and HBV;

(d) if so, the reasons therefor;

(e) whether the Government proposes to assign the said job to one of the departments of the Ministry of Health; and

(f) if so, the details in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): Yes Sir.

NTPC as Procurement support agent for NACO has in the past procured diagnostics test kits. Their contract concluded on 31.3.2005

(b): The guidelines for quality assurance of test kits is annexed at Annexure `A`.

A statement detailing the costs of these test kits is annexed at Annexure `B`.

(c) & (d): Yes Sir.

As detailed in Annexure `A`, quality checks for HIV and HCV kits were made by NTPC during their initial contract period with the help of consultant doctors from NTPC / AIIMS. After 30.10.2003 the quality tests are carried out at any one of three laboratories identified by NACO viz., NARI, Pune or NICD, Delhi or CMC Hospital, Vellore. HBV kits are not procured centrally by NACO. Hence NTPC did not procure HBV kits.

(e) & (f): Yes Sir. Since 1.4.2005, NACO has appointed Hindustan Latex Ltd. (HLL), a Govt. of India undertaking under the Ministry of Health & Family Welfare as procurement Agent.

Annexure-A

Guidelines for quality assurance of test kits procured under NACP - II:

I. Till 30th October 2003:

A. For Indigenous Test Kits :

The Quality Plan / Inspection Checklist is finalised by NTPC along with their Consultant Doctors from NTPC / AIIMS with the supplier covering various stages of manufacture i.e. right from the raw material procurement to final readiness to ensure Kits be of best quality and in line with technical specifications. After Kits are finally produced and all internal testing etc. carried out by supplier, the Physical Inspection is carried out by NTPC Inspection Engineer along with their Consultant Doctor, wherein kits are randomly selected and tested in person. Kits are allowed to be despatched only upon successful completion of Inspection and thereby ascertaining their meeting the technical specifications.

B. For Foreign Test Kits :

The Quality Plan/ Inspection Checklist is finalised by NTPC along with their Consultant Doctors from NTPC / AIIMS with the supplier covering various stages of manufacture i.e. right from the raw material procurement to final readiness to ensure Kits be of best quality and in line with technical specifications. After Kits are finally produced and all internal testing etc. carried out by supplier, the test

certificates are furnished by supplier to NTPC for their review. All the Test certificates (for stage as well as on finished product) furnished by supplier are examined and reviewed in line with approved Quality Plan. Despatch clearance is given after acceptance of same.

In case certain discrepancies are noted in same, the views of NTPC consultant doctors from AIIMS are obtained and despatch clearance is accorded only after total resolution of all queries.

II. After 30th October 2003 for both types of kits:

All test kits are subject to pre-despatch inspection. These inspections are carried out in any one laboratory located at NARI, Pune or NICD, Delhi or CMC Hospital, Vellore. Samples are drawn by a representative of the procurement agency. In case the results are disputed by the supplier fresh samples from the same batch would be forwarded to NIB, NOIDA for appellate evaluation, the results of which would be binding on both NACO and the supplier.
Annexure `B`.

Sl. No.	Type of kit	Average Cost per test as per latest contracts
1	HIV (ELISA)	Rs. 9.82
2	HIV (Rapid)	Rs. 15.44
3	HCV (ELISA)	Rs. 9.17